ISRCTN62822052 https://doi.org/10.1186/ISRCTN62822052

An innovative early intervention for antisocial children with callous-unemotional traits

Submission date
20/06/2011

Recruitment status
No longer recruiting

Registration date
22/08/2011

Overall study status
Completed

Last Edited
14/12/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Serious and persistent antisocial behaviour is a widespread problem, with latest figures (Office of National Statistics, 2004) indicating a prevalence of 5% of children in the United Kingdom. Antisocial behaviour that begins in childhood tends to follow a severe, chronic course, with these early starters placed at increased risk for violent behaviours, unemployment, substance abuse and criminal offending. It is the most common reason for referral to child mental health services and the most reliable predictor of all types of adult mental health problems. One UK study has shown that by the age of 28, children with severe antisocial behaviour cost society ten times more than healthy children, due to the burden on justice, education and social services (Scott, et al., 2001). The enormous personal and financial cost of antisocial behaviour highlights the need for effective early intervention programs. Children with high levels of callous-unemotional (CU) traits are at greater risk for severe and chronic antisocial behaviour, including violence and criminal offending. CU traits are characterized by low levels of empathy, guilt and emotionality and reduced arousal. Parent-training (PT) involves providing parents with discipline (e.g., 'time-out') and reward strategies and is the most effective treatment currently available for child antisocial behaviour. However, PT is limited in its effectiveness for these high-risk children, highlighting the need to tailor intervention to individual child characteristics. Children high in CU traits have difficulty recognising facial expressions (e.g., fear) compared to antisocial children low in these traits. These difficulties appear to be driven by lack of attention (i.e., eye gaze) to emotional cues. However, children's accuracy in emotion recognition can be improved simply by encouraging them to gaze towards the eye region of others' faces (Dadds et al., 2006). These difficulties in attending to and recognising the emotions of others are likely to begin early in life, with a failure to pay attention to and benefit from shared emotional events with caregivers. Gentle discipline and reward strategies that promote the parent-child relationship (e.g., affection, praise, warmth) have been associated with improved child behaviour. In contrast, harsh discipline and punitive responses to children's expression of emotion are associated with poor outcomes, including low empathy. Therefore enhancing parent-child warmth, sensitivity and eye contact during emotional interactions represents a promising alternative route for early intervention with these at-risk children.
The current study will conduct the first trial of a new treatment targeting parent-child 'emotional engagement' (EE) designed specifically for children that are relatively resistant to existing evidence-based interventions for antisocial behaviour. We predict that a brief

manualised intervention that is adjunctive to traditional parent training (Dadds & Hawes, 2006) and focuses on parent-child emotional engagement/eye contact will produce better outcomes to standard parent training. The comparison condition will consist of standard parent training plus a 'control' adjunct to ensure that any differences between the two comparison groups are not due to non-specific effects of parent-child attention or therapist time.
This study aims to answer questions such as: Will the EE intervention be socially acceptable to and well implemented by parents of antisocial children? Will the EE intervention will lead to improvements in parent-child emotional engagement over and above those produced by standard parent training plus the control adjunct? And will the changes associated with EE produce improvements in the behaviour, empathy and emotion understanding in antisocial children with high CU traits? This study also aims to investigate whether certain parent and child genotypes are associated with different treatment outcomes (e.g., parenting, child behaviour). Parent and child physiological reactions and how they relate to parenting, parent outcomes and child behavioural outcomes will also be determined.

Who can participate?
Children aged 3 to 8 years of age whose main problem is oppositional and defiant behaviour and their parents will be invited to participate. Advertisements for the programme will be placed in newspapers distributed in south London. Parents who contact the research team will be provided with further information and complete a brief screening interview over the phone to determine their eligibility for the study. Children with psychosis, autism, significant developmental delay or a severe medical problem are not eligible to participate. Families are not eligible to participate if they are receiving concurrent medication or psychiatric treatment or if there is child protection plan in place. Parents and children must also be fluent in English and able to attend the assessment and treatment sessions at the Institute of Psychiatry, King's College London, Denmark Hill campus. Families who are not eligible for the study will be referred to the appropriate agencies.

What does the study involve?
Following the phone screening interview, parents will be invited to meet a clinician for an interview as a final check for eligibility and to develop a plan for treatment. Parents will be given questionnaires assessing their child's behaviour and characteristics of their family (e.g., parenting practices, parent well-being). Teacher questionnaires will assess child behaviour in the school or nursery setting. Parents and children will be invited to attend a research session to assess child moral understanding, emotion recognition and language ability. Parents and children will do some activities together to assess the quality of the parent-child relationship and eye contact between parent and child. Parent and child heart rate measurements will be monitored using a bioharness (strap-on belt) during these activities to examine levels of emotional arousal. DNA will be taken from children and parents (if a biological parent) using a cheek swab.
Following the clinical interview and research session, families will be randomly allocated to one of two programmes and will meet with a clinician for 6 sessions of treatment on a weekly basis (1.5 hours each session). Children will attend three sessions to enable in-session practice of the strategies and therapist feedback. The EE programme will consist of a discussion of how the child reacts to parental love and eye contact, and how the parent feels about expressing it. Parents are instructed to engage with their child and then, looking deeply into their child's eyes, express their love as naturally as they can. The interaction is videotaped. Positive and negative aspects of the interaction are identified and goals are set for improvement. The parents are asked to ensure that these moments of close engagement with expressions of love and eye contact are used at least once a day. The control adjunct consists of videotaping of parent-child play, followed by discussion and therapist feedback, and standard child management techniques of praise and behaviour correction (if needed) during a parent-child 'free play' then 'clean up'

scenario. Parents are asked engage in free play at least once a day. Parents in both treatment conditions will complete self-monitoring forms to assess parents' use of the strategies. The clinical interview, questionnaires and research session will be repeated at the end of the programme and three months later so that we can assess whether the programme was successful in improving child outcomes.

What are the possible benefits and risks of participating?
Information gained from this study may help professionals and other parents and their children. Even though children with high levels CU traits show reduced responsiveness to parent training, there are currently no treatments designed specifically for high CU children. Families are offered one-on-one clinical expertise otherwise unavailable to them without a referral. The style of parenting programme we are offering to eligible participants is regarded as the most effective treatment currently available for child behaviour problems, with approximately 65% of families typically achieving significant and long-lasting improvements. However, we cannot guarantee that participants will receive any benefits from the programme.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
Recruitment will commence in August 2011 and it is anticipated that the study will be completed in August 2013.

Who is funding the study?
Guy's and St Thomas' Charity (UK)

Who is the main contact?
Dr Jennifer Allen
jennifer.allen@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Mark Dadds

Contact details
Dept. of Child and Adolescent Psychiatry
Institute of Psychiatry
King's College London
PO 85 De Crespigny Park
London
United Kingdom
SE5 8AF
-
m.dadds@unsw.edu.au

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An innovative early intervention for antisocial children with callous-unemotional traits: a randomised controlled trial

Study objectives
The aim is to trial a new treatment for children with high levels of callous-unemotional (CU) traits who are relatively resistant to existing evidence-based interventions for conduct problems (CP) by targeting parent-child emotional engagement (EE).

Specific hypotheses are :
1. The EE intervention will be acceptable to and well implemented by parents of children referred with CP
2. The EE intervention will lead to systematic changes in parent-child emotion engagement over and above those produced by current best practice interventions
3. Changes associated with EE will produce improvements in child outcomes in children with CP and high CU traits

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint Schools Research Ethics Sub-Committee for the Institute of Psychiatry, King's College London, 19/05/2011, ref: PNM/10/11-121

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Conduct and oppositional defiant disorder

Interventions
The study will compare standard parent training (PT) plus an emotional engagement (EE) adjunct to parent training plus a control adjunct (behavioural child play).

PT comprises the Dadds and Hawes (2006) programme, an evidence-based intervention with a long empirical history in the treatment of CP. It consists of six 1.5 hour treatment sessions that focus on managing child aggression, noncompliance, and disruptive behaviour, as well as modules on parental mental health, marital adjustment and family communication.

PT+ EE consists of this programme with the addition of the following: In three sessions, the final ten minutes is devoted to a discussion of how the child reacts to parental love and eye contact, and how the parent feels about expressing it. The instruction above is then given to the parent (s) to engage with the child and then, looking deeply into the child's eyes, express their love as naturally as they can. The interaction is videotaped.

At the next session, the 10 minute discussion includes watching the previous week's interaction according to the principals of Video Interactive Guidance (VIG: Fukkink, 2008); that is, positive and negative aspects of the interaction are identified and goals are set for improvement. The parents are asked to ensure that these moments of close engagement with expressions of love and eye contact are used at least once a day. Self-monitoring logs monitor parents' use of these activities and overall 'dose' per parent/family.

The PT group will be given a 'control' intervention to make sure any advantages found for EE are not due to non-specific factors. Thus, the final 10 minutes of three PT sessions will be devoted to discussion, videotaping and VIG, of standard child management techniques of praise and behaviour correction (if needed) during a parent-child 'free play' then 'clean up' scenario. The parents are asked engage in free play at least once a day. Self-monitoring logs monitor parents' use of these activities and 'dose' per parent/family. This 'control' intervention is highly acceptable to parents, leads to nonspecific improvements in parent-child interaction, but has no effect on CU traits.

Intervention Type
Behavioural

Primary outcome measure
1. Clinician-based diagnoses and severity ratings will be provided using the Diagnostic Interview for Children, Adolescents and Parents: Parent version (Holland & Dadds, 1997)
2. Callous-unemotional traits and conduct problems will be assessed using parent and teacher report on the Antisocial Process Screening Device and the Strengths and Difficulties Questionnaire.
Assessments will be conducted pre-treatment, post-treatment (1-2 weeks following the intervention) and at a 3-month follow-up

Secondary outcome measures

Secondary outcomes will be assessed at pre-treatment, post-treatment (1-2 weeks following treatment) and at a 3-month follow-up. The assessment protocol is multimethod, and includes questionnaires, tests, a computer-administered facial emotion recognition task, observational measures of parent-child interaction and biological measures.
1. Sociodemographic information
2. Child adjustment
2.1. Child Asperger Symptom Test
2.2. Spence Anxiety Scale
2.3. Affect Intensity Scale
3. Parental adjustment
3.1. Depression Anxiety Stress Scales
3.2. Psychopathic Profiles Inventory
4. Parenting practices
4.1. Alabama Parenting Questionnaire
4.2. Coping with Childrens Negative Emotions Scale
5. Child emotional competence
5.1. Griffith Empathy Measure
5.2. Faces: Age Categorised Emotional Stimuli
5.3. Test of Emotion Comprehension
5.4. Moral Story Stems Battery
6. Parent-child relationship quality
6.1.Self-Expressiveness in the Family Questionnaire
6.2. I-Love-You
6.3. Parent-child free play
7. Family environment
7.1. Self-Expressiveness in the Family Questionnaire
7.2. Quality of the Family Environment Scale
8. Child language
8.1. British Picture Vocabulary Scales
9. Feasibility and acceptance of adjuncts
9.1. Parent monitoring forms
9.2. Strategy rating form
9.3. Adjunct feedback forms
10. Biological measures
10.1. Child and biological parent DNA will be taken using cheek swabs
10.2. Child and parent heart rate will be monitored using a bioharness at baseline and during parent-child interaction

Overall study start date
01/07/2011

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Child aged 3-8 years, either sex
2. Primary diagnosis of conduct or oppositional defiant disorder

Participant type(s)

Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
60 children and their parents

Key exclusion criteria
1. No current diagnosis of psychosis, primary autism, developmental delay or major medical disorder
2. No concurrent medication or psychiatric treatment
3. Primary caregiver lack of fluency in English, severe psychiatric illness or addiction
4. Presence of a child protection plan

Date of first enrolment
01/08/2011

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
Guy's and St Thomas' Charity (UK)

Sponsor details
c/o Maria Abelleira
1st Floor, Counting House
Great Maze Pond
Guy's Hospital
London
United Kingdom
SE1 9RT
+44 (0)20 7188 1231
maria.abelleira@gsttcharity.org.uk

Sponsor type
Charity

Website
http://www.gsttcharity.org.uk

ROR
https://ror.org/02p7svq74

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity (UK)

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration